# PRIOR AUTHORIZATION FOR PREFERRED SPECIALTY MANAGEMENT POLICY

**POLICY:** Hepatitis C – Mavyret Prior Authorization for Preferred Specialty Management Policy
- Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets – AbbVie)

**REVIEW DATE:** 04/05/2023

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***INSTRUCTIONS FOR USE***

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## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Mavyret, a direct-acting antiviral, contains glecaprevir, a pangenotypic NS3/4A protease inhibitor and pibrentasvir, a pangenotypic NS5A inhibitor.[1] It is indicated for the treatment of **chronic hepatitis C virus** (HCV) in the following scenarios:
- Patients ≥ 3 years of age with genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- Patients ≥ 3 years of age with genotype 1 infection who have previously been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

### Dosing

The duration of therapy is based on prior treatment experience, genotype, and the presence or absence of cirrhosis (see Tables 1 and 2). In addition, Mavyret is Non-Preferred Product for 12 weeks in patients ≥ 3 years of age who are liver or kidney transplant recipients. Similar to non-transplant recipients, a 16-week treatment duration is Non-Preferred Product in genotype 1-infected patients who are NS5A inhibitor-experienced without prior treatment with an NS3/4A protease inhibitor or in genotype 3-infected patients who are treatment-experienced with regimens

containing interferon, pegylated interferon, ribavirin, and/or Sovaldi® (sofosbuvir tablets/oral pellets).

**Table 1. Recommended Duration for Treatment-Naïve Patients.[1]**

| HCV Genotype | Treatment Duration | |
|---|---|---|
| | No Cirrhosis | Compensated Cirrhosis (Child-Pugh A) |
| 1, 2, 3, 4, 5, or 6 | 8 weeks | 8 weeks |

HCV – Hepatitis C virus.

**Table 2. Recommended Duration for Treatment-Experienced Patients.[1]**

| HCV Genotype | Prior Treatment Experience | Duration | |
|---|---|---|---|
| | | Without Cirrhosis | With Compensated Cirrhosis (Child-Pugh A) |
| 1, 2, 4, 5, 6 | PRS | 8 weeks | 12 weeks |
| 3 | PRS | 16 weeks | 16 weeks |
| 1 | NS3/4 PI[1] (NS5A-naïve) | 12 weeks | 12 weeks |
| | NS5A inhibitor[2] (NS3/4 PI-naïve)[†] | 16 weeks | 16 weeks |

HCV – Hepatitis C virus; PRS – Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi® (sofosbuvir tablets), but no prior treatment experience with an HCV NS3/4A protease inhibitor (PI) or NS5A inhibitor; PI – Protease inhibitor; [1] Regimens containing Olysio® (simeprevir capsules) and Sovaldi, or Olysio, Victrelis® (boceprevir capsules), or Incivek® (telaprevir tablets) with interferon or pegylated interferon and ribavirin were studied; [2] Regimens containing ledipasvir/sofosbuvir or Daklinza® (daclatasvir tablets) + pegylated interferon + ribavirin [unapproved regimen] were studied.

## Guidelines

The American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) provide recommendations for testing, monitoring, and treating HCV (October 24, 2022).[2] Instances in which the guidelines provide recommendations for Mavyret outside of the FDA-approved indications are outlined below.

With the availability of pangenotypic HCV treatment regimens, HCV genotyping is no longer required prior to treatment initiation for all individuals.[2] Pretreatment genotyping is still Non-Preferred Product in patients with cirrhosis and/or past unsuccessful HCV treatment, because treatment regimens may differ by genotype. However, for treatment-naïve patients without cirrhosis, although genotyping may impact the preferred treatment approach, it is not required if a pangenotypic regimen is used. In treatment-naïve adults without cirrhosis, the Non-Preferred Product regimens are Mavyret for 8 weeks or sofosbuvir/velpatasvir for 12 weeks. Additional genotype-specific and/or special circumstance-specific recommendations are also provided for patients falling outside of these parameters. Mavyret is recognized as a Non-Preferred Product regimen (12 weeks) for the treatment of patients with recurrent HCV post-liver transplantation (without cirrhosis or with compensated cirrhosis).

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Mavyret. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Mavyret as well as the monitoring required for adverse events and efficacy, approval requires Mavyret to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets - AbbVie)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1.** Approve for the duration noted if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Approve for 12 weeks if the patient meets ONE of the following criteria (a or b):
       - **a)** Patient is treatment-naïve; OR
       - **b)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek (telaprevir tablets), Olysio (simeprevir capsules), or Victrelis (boceprevir capsules); OR
     - **ii.** Approve for 16 weeks if the patient meets ONE of the following criteria (a, b, or c):
       - **a)** Patient has previously been treated with Daklinza (daclatasvir tablets), sofosbuvir/velpatasvir, ledipasvir/sofosbuvir, or Zepatier (elbasvir/grazoprevir tablets); OR
       - **b)** Patient has previously been treated with Sovaldi (sofosbuvir tablets/oral pellets) + ribavirin with or without pegylated interferon/interferon; OR
       - **c)** Patient has previously been treated with Sovaldi + Olysio; AND
   - **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV) Genotype 2.** Approve for 12 weeks if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

3. **Chronic Hepatitis C Virus (HCV) Genotype 3.** Approve for the duration noted if the patient meets the following criteria (A, B, and C):

**A)** Patient is ≥ 3 years of age; AND
**B)** Patient meets ONE of the following criteria (i or ii):
  **i.** Approve for 12 weeks if the patient is treatment-naïve; OR
  **ii.** Approve for 16 weeks if the patient meets the following criteria (a or b):
    **a)** Patient has previously been treated with Sovaldi (sofosbuvir tablets/oral pellets) + ribavirin with or without pegylated interferon/interferon; OR
    **b)** Patient has previously been treated with pegylated interferon/ribavirin; AND
**C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

4. **Chronic Hepatitis C Virus (HCV) Genotype 4.** Approve for 12 weeks if the patient meets the following criteria (A and B):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

5. **Chronic Hepatitis C Virus (HCV) Genotype 5 or 6.** Approve for 12 weeks if the patient meets the following criteria (A and B):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

6. **Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]).** Approve for the duration noted if the patient meets the following criteria (A, B, and C):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** Patient meets ONE of the following criteria (i or ii):
     **i.** Approve for 12 weeks if the patient meets ONE of the following criteria (a or b):
       **a)** Patient is treatment-naïve; OR
       **b)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek (telaprevir tablets), Olysio (simeprevir capsules), or Victrelis (boceprevir capsules); OR
     **ii.** Approve for 16 weeks if the patient meets ONE of the following criteria (a, b, or c):
       **a)** Patient has previously been treated with Daklinza (daclatasvir tablets), sofosbuvir/velpatasvir, ledipasvir/sofosbuvir, or Zepatier (elbasvir/grazoprevir tablets); OR
       **b)** Patient has previously been treated with Sovaldi (sofosbuvir tablets/oral pellets) + ribavirin with or without pegylated interferon/interferon; OR
       **c)** Patient has previously been treated with Sovaldi + Olysio; AND
   **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician.

7. **Hepatitis C Virus (HCV) Genotype 4 with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]).** Approve for 12 weeks if the patient meets all of the following criteria (A and B):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician.

8. **Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6 with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]).** Approve for the duration noted if the patient meets the following criteria (A, B, and C):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** Patient meets ONE of the following criteria (i, ii, or iii):
      **i.** Patient has genotype 2, 5, or 6: Approve for 12 weeks; OR
      **ii.** Patient has genotype 3 and is treatment-naïve: Approve for 12 weeks; OR
      **iii.** Patient has genotype 3 and has previously been treated: Approve for 16 weeks; AND
   **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician.

9. **Hepatitis C Virus (HCV) Genotype 1, Kidney Transplant.** Approve for the duration noted if the patient meets the following criteria (A, B, C, and D):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** Patient is a kidney transplant recipient; AND
   **C)** Patient meets ONE of the following criteria (i or ii):
      **i.** Patient is treatment-naïve: Approve for 12 weeks; OR
      **ii.** Patient has previously been treated for HCV: Approve for 16 weeks; AND
   **D)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, nephrologist, renal transplant physician, or liver transplant physician.

10. **Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6, Kidney Transplant.** Approve for the duration noted if the patient meets the following criteria (A, B, C, and D):
   **A)** Patient is ≥ 3 years of age; AND
   **B)** Patient is a kidney transplant recipient; AND
   **C)** Patient meets ONE of the following criteria (i, ii, or iii):
      **i.** Patient has genotype 2, 5, or 6: Approve for 12 weeks.
      **ii.** Patient has genotype 3 and is treatment-naïve: Approve for 12 weeks.
      **iii.** Patient has genotype 3 and has previously been treated for HCV: Approve for 16 weeks; AND

**D)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, nephrologist, renal transplant physician, or liver transplant physician.

**11. Hepatitis C Virus (HCV) Genotype 4, Kidney Transplant.** Approve for 12 weeks if the patient meets the following criteria (A, B, and C):

**A)** Patient is ≥ 3 years of age; AND

**B)** Patient is a kidney transplant recipient; AND

**C)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, nephrologist, renal transplant physician, or liver transplant physician.

**12. Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant.** Approve for the duration noted below if the patient meets the following criteria (A, B, C, and D):

**A)** Patient is ≥ 3 years of age; AND

**B)** Patient is a liver transplant recipient; AND

**C)** Patient meets ONE of the following (i, ii, or iii):

**i.** Patient has genotype 2, 4, 5, or 6: Approve for 12 weeks.

**ii.** Patient has genotype 1 or 3 and is treatment-naïve: Approve for 12 weeks.

**iii.** Patient has genotype 1 or 3 and has previously been treated for HCV: Approve for 16 weeks; AND

**D)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

**Other Uses with Supportive Evidence**

**13. Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1, 2, 3, 4, 5, or 6.** Approve for 12 weeks if the patient meets the following criteria (A, B, and C):

**A)** Patient is ≥ 3 years of age; AND

**B)** Patient has recurrent HCV after a liver transplantation; AND

**C)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, or liver transplant physician.

**14. Patient Has Been Started on Mavyret.** Approve for an indication or condition above. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

## CONDITIONS NOT COVERED

- **Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets - AbbVie)**

**is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. **Hepatitis C Virus (HCV) Child-Pugh Class B or C Liver Disease (Moderate or Severe Hepatic Impairment).** Mavyret is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh Class B or C).

2. **Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs).** Mavyret provides a complete antiviral regimen.

3. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** Patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy do not require antiviral treatment.[2] Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert. Little evidence exists to support initiation of HCV treatment in patients with a limited life expectancy (< 12 months) owing to non-liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized and palliative care strategies should take precedence.

4. **Pediatric Patients (Age < 3 Years of Age).** The safety and efficacy of Mavyret have not been established in pediatric patients < 3 years of age.[1]

## REFERENCES


1. Mavyret® tablets and oral pellets [prescribing information]. North Chicago, IL: AbbVie; September 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: http://www.hcvguidelines.org. Updated October 24, 2022. Accessed on March 24, 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | Mavyret oral pellets were added to the policy. Throughout the policy, where listed, "Epclusa (brand or generic)" was changed to "sofosbuvir/velpatasvir" and "Harvoni (brand or generic)" was changed to "ledipasvir/sofosbuvir". For the durations of approval "up to" was removed; all approvals are for the durations previously stated within the policy.<br>**Chronic Hepatitis C Virus (HCV) Genotype 1:** Age of approval was changed to ≥ 3 years of age.<br>**Chronic Hepatitis C Virus (HCV) Genotype 2:** Age of approval was changed to ≥ 3 years of age.<br>**Chronic Hepatitis C Virus (HCV) Genotype 3:** Age of approval was changed to ≥ 3 years of age.<br>**Chronic Hepatitis C Virus (HCV) Genotype 4:** Age of approval was changed to ≥ 3 years of age.<br>**Chronic Hepatitis C Virus (HCV) Genotype 5 or 6:** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]):** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 4 with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]):** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6 with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]):** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 1, Kidney Transplant:** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6, Kidney Transplant:** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 4, Kidney Transplant:** Age of approval was changed to ≥ 3 years of age.<br>**Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant:** Age of approval was changed to ≥ 3 years of age.<br>**Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1, 2, 3, 4, 5, or 6:** Age of approval was changed to ≥ 3 years of age.<br>**Pediatric Patients (Age < 12 Years or < 45 kg):** The age was revised to < 3 years of age and weight was removed from this "Condition not Non-Preferred Product for Approval". | 06/16/2021 |
| Annual Revision | No criteria changes. | 06/08/2022 |